



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,714	02/20/2004	Huddee Jacob Ho	MNOAP006	5606
23689	7590	07/19/2006	EXAMINER	
Jung-hua Kuo Attorney At Law PO Box 3275 Los Altos, CA 94024			TOY, ALEX B	
			ART UNIT	PAPER NUMBER
			3739	

DATE MAILED: 07/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/783,714

Applicant(s)

HO ET AL.

Examiner

Alex B. Toy

Art Unit

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 and 23-33 is/are pending in the application.
- 4a) Of the above claim(s) 2, 3, 5, 9, 10, 12-14, 19 and 28-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4, 6-8, 11, 15-18, 20, 21, 23-27, 32 and 33 is/are rejected.
- 7) ☒ Claim(s) 15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 May 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

This Office Action is in response to applicant's reply filed on May 1, 2006. The objection to the drawings is withdrawn in view of applicant's amendment and cancellation of claims 22 and 34. The 35 U.S.C. 112, first paragraph rejections are withdrawn in view of applicant's cancellation of claims 22 and 34.

Claim Objections

Claim 15 is objected to because of the following informalities: In line 4, "penetrating configuration" should be changed to – cutting configuration –. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 6-8, 16-17, and 20-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Burbank (U.S. Pat. No. 6,331,166).

Regarding claim 1, Burbank discloses a tissue cutting device, comprising:

a probe 18a having a length generally defining a probe axis 19a, the probe defining at least one cutting loop exit 66 at an exit angle relative to the probe axis, the exit being at a distal region of the probe (Figs. 17-19);

a cutting loop 20a with shape memory having a preconfigured shape (col. 4, In. 60-62, col. 7, In. 6-7, and col. 8, In. 3-7), the cutting loop being selectively in one of a penetrating configuration configured for the cutting device to penetrate tissue (Fig. 17) and a cutting configuration configured for the cutting loop to cut tissue (Fig. 18), the cutting loop being generally within a profile of the probe in the penetrating configuration (Fig. 17), and when in the cutting configuration, the cutting loop extends through the cutting loop exit and generally returns to the preconfigured shape and generally defines a cutting configuration plane (Fig. 18), the cutting loop being at a cutting angle relative to the probe axis generally defined by the exit angle and the probe axis being non-parallel to the cutting configuration plane (col. 8, In. 3-32 and Figs. 17-18); and

a cutting loop securing mechanism (proximal control mechanism – not shown) configured to selectively secure the cutting loop 20a in the penetrating configuration and to release the cutting loop into the cutting configuration, the cutting loop securing mechanism being one of slidably disposed relative to the probe (col. 8, In. 14-30 and Figs. 17-18) and a groove defined in the probe proximal to the cutting loop exit.

Although the cutting loop securing mechanism of Burbank is not shown, it must be inherently slidably disposed relative to the probe since the entire cutting loop slides relative to the probe (Fig. 18).

Regarding claim 6, Burbank discloses the device of claim 1, wherein the probe includes at least one cutting loop channel terminating at the cutting loop exit (col. 8, ln. 12-19 and Figs. 17-18).

Regarding claim 7, Burbank discloses the device of claim 1, wherein the size of the cutting loop is adjustable by retracting or extending the cutting loop into and out of the probe when the cutting loop is in a cutting configuration (col. 8, ln. 34-38 and Fig. 19).

Regarding claim 8, Burbank discloses the device of claim 1, wherein the probe defines two cutting loop exits through which the cutting loop extends (Fig. 18). Since the cutting loop is able to slide axially, inherently there must be a second exit not shown that is opposite the shown exit 66.

Regarding claim 16, Burbank discloses the device of claim 1, wherein the cutting loop 20a is coupled to an energy source configured to supply energy to the cutting loop to facilitate cutting of tissue by the cutting loop (col. 8, ln. 14-25).

Regarding claim 17, Burbank discloses the device of claims 1 and 16, wherein the energy source is selected from at least one of a radio frequency, laser, water jet, air abrasion, ultrasonic, oscillation along a predetermined distance, direction and/or frequency, oscillation along a variable distance, direction and/or frequency (col. 8, ln. 14-25).

Regarding claim 20, Burbank discloses the device of claim 1, further comprising a probe locating mechanism housed in the probe, the probe locating mechanism facilitates in determining the location of at least one of the probe and the cutting loop

within the tissue from external to the tissue, the probe locating mechanism being one of a light, a radiologic marker, and an ultrasound marker (col. 5, ln. 24-31). Since Burbank discloses using ultrasound as a probe locating mechanism, the probe of Burbank must inherently comprise a probe locating mechanism in the probe.

Regarding claim 21, Burbank discloses the device of claim 1, further comprising a tissue collector to collect tissue cut by the cutting loop (col. 8, ln. 39-46).

Claims 23-24 and 32-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Dulebohn (U.S. Pat. No. 5,201,741).

Regarding claim 23, Dulebohn discloses a method for cutting targeted tissue, comprising:

positioning a tissue cutting device 10 adjacent to the targeted tissue, such that a distal end 52 of a probe 50 of the tissue cutting device is distal to the targeted tissue, the probe having a length generally defining a probe axis and the probe defining at least one cutting loop exit 54 at an exit angle relative to the probe axis, the exit being at a distal region of the probe;

releasing 58 a cutting loop 16 of the tissue cutting device from being generally parallel to the probe axis in a penetrating configuration to a cutting configuration, the cutting loop being in soft tissue during the release, the cutting loop having shape memory (col. 4, ln. 42-48) with a preconfigured shape such that upon releasing the cutting loop, the cutting loop generally returns to the preconfigured shape and generally extends at a cutting angle relative to the probe axis defined by the exit angle (col. 7, ln. 57-62); and

retracting the tissue cutting device so that the cutting loop in the cutting configuration cuts the targeted tissue (col. 3, ln. 1-9).

See Figs. 8-9.

Regarding claim 24, Dulebohn discloses the tissue cutting method of claim 23, further comprising returning the cutting loop to the penetrating configuration when the cutting loop is proximal to the targeted tissue (col. 3, ln. 6-11).

Regarding claim 32, Dulebohn discloses the tissue cutting method of claim 23, further comprising adjusting the size of the cutting loop to generally encircle the targeted tissue (col. 3, ln. 1-6).

Regarding claim 33, Dulebohn discloses the tissue cutting method of claim 23, wherein the retracting is such that a tissue collector follows the path of the cutting loop to collect the cut tissue (col. 3, ln. 6-11 and col. 7, ln. 45-55). In the device of Dulebohn, the cutting loop 16 also serves as the tissue collector.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

Art Unit: 3739

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 4, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doll (U.S. Pat. No. 5,078,716) in view of Suzuki (U.S. Pat. No. 6,068,603)

Regarding claim 1, Doll discloses a tissue cutting device, comprising:

a probe 110 having a length generally defining a probe axis, the probe defining at least one cutting loop exit at 114 at an exit angle relative to the probe axis, the exit being at a distal region of the probe (Fig. 4);

a cutting loop 126 with shape memory having a preconfigured shape (col. 8, ln. 40-44 and Figs. 6-8), the cutting loop being selectively in one of a penetrating configuration configured for the cutting device to penetrate tissue and a cutting configuration configured for the cutting loop to cut tissue, the cutting loop being generally within a profile of the probe in the penetrating configuration, and when in the cutting configuration, the cutting loop extends through the cutting loop exit and generally returns to the preconfigured shape and generally defines a cutting configuration plane, the cutting loop being at a cutting angle relative to the probe axis generally defined by the exit angle (col. 6, ln. 35 – col. 7, ln. 7); and

a cutting loop securing mechanism 150 configured to selectively secure the cutting loop 126 in the penetrating configuration and to release the cutting loop into the cutting configuration, the cutting loop securing mechanism being one of slidably

Art Unit: 3739

disposed relative to the probe 110 (col. 6, ln. 51-54) and a groove defined in the probe proximal to the cutting loop exit.

The claim differs from Doll in calling for the probe axis to be non-parallel to the cutting configuration plane. Suzuki, however, teaches an analogous electrosurgical snare, wherein the probe axis is non-parallel to the cutting configuration plane (Figs. 1B, 2A, and 4A). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the probe axis non-parallel to the cutting configuration plane in the device of Doll in view of the teaching of Suzuki as an obvious alternate snare shape/configuration that is known in the art to be effective for removing polyps. In addition, Doll discloses that the loop 126 may be pre-bent to assume a desired shape (col. 8, ln. 41-43).

Regarding claim 4, Doll discloses the device of claim 1 in view of Suzuki. In addition, Doll discloses the device, wherein the cutting loop securing mechanism 150 is a cover slidably disposed over probe 110 and configured to secure the cutting loop 126 between the loop cover and the probe for the penetrating configuration (col. 6, ln. 51-54).

Regarding claim 15, Doll discloses the device of claim 1 in view of Suzuki. In addition, Doll discloses the device, further comprising a loop cover 150 disposed slidably over probe 110, the loop cover configured to secure the cutting loop between the loop cover and the probe for the penetrating configuration and to release the cutting loop into its preconfigured shape for the cutting configuration (col. 6, ln. 51-54).

Claims 11 and 18 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Burbank ('166).

Regarding claim 11, Burbank discloses the device of claim 1. Since Burbank discloses that element 20a is a cutter (col. 8, ln. 14-15), it would be obvious, if not inherent, to have at least one edge of the cutting loop to be at least one of sharpened and serrated in order to facilitate cutting.

Regarding claim 18, Burbank discloses the device of claims 1 and 16, wherein the cutting loop 20a is partially insulated 18a to selectively expose the tissue to the energy (Fig. 18). It would be obvious, if not inherent, for the shaft 18a to be made from an insulating material so that treatment only occurs at the electrodes as is well-known in the art.

Claims 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dulebohn ('741) in view of Burbank ('166).

Regarding claim 25, Dulebohn discloses the tissue cutting method of claim 23. The claim differs from Dulebohn in calling for applying an energy to the cutting loop to facilitate cutting of tissue during the retracting. Burbank, however, teaches a surgical snare and applying an energy to the cutting loop to facilitate cutting of tissue (col. 4, ln. 64-66). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have applied an energy to the cutting loop of Dulebohn in view of the teaching of Burbank in order to facilitate cutting of tissue during the retracting.

Regarding claim 26, Dulebohn discloses the tissue cutting method of claims 23 and 25 in view of Burbank. In addition, Burbank teaches that the energy comprises radio frequency energy, a type of energy that is well-known in the art.

Regarding claim 27, Dulebohn discloses the tissue cutting method of claims 23 and 25 in view of Burbank. 27. Given that the method of Dulebohn selectively exposes the cutting loop (Fig. 8) and that Burbank teaches that his cutting loop is partially insulated 30 to selectively expose the tissue to the energy being applied (Figs. 8-10), it would be obvious to partially insulate the energized device of Dulebohn in view of Burbank in order to selectively expose the tissue to the energy being applied.

Response to Arguments

Applicant's arguments with respect to claims 1, 4, 6-8, 11, 15-18, and 20-21 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments with respect to claims 23-27 and 32-33 have been fully considered but they are not persuasive.

Regarding amended independent claim 23, applicant argues that the cutting loop of Dulebohn is in air and not in soft tissue during its release. While the cutting loop of Dulebohn may be in an air cavity, it is still disposed inside the body and therefore "in soft tissue during the releasing".

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

US 4503855 A	USPAT	Maslanka; Harald
US 5171233 A	USPAT	Amplatz; Kurt et al.
US 6123665 A	USPAT	Kawano; Hironobu

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alex B. Toy whose telephone number is (571) 272-1953. The examiner can normally be reached on Monday through Friday, 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AT *AT*
7/11/06

Michael Peffley
MICHAEL PEEFLEY
PRIMARY EXAMINER